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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/306,780	05/07/1999	FUMINORI TAKEMURA	2084-0046-0D	3946
22850	7590	10/19/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			HINES, JANA A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/306,780	TAKEMURA ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28,30 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30 and 32 is/are allowed.
- 6) ☒ Claim(s) 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. The amendment filed July 7, 2004 has been entered. Claim 28 has been amended. Claims 1-27, 29, 31 and 33-40 have been canceled. Claims 28, 30 and 32 are under consideration in this office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

- a) The rejection of claims 25-40 under 35 U.S.C. 112, second paragraph; and
- b) The rejection of claims 25-27 and 33-35 under 35 U.S.C. 103(a).

Response to Arguments

3. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al., (US Patent 4,749,647) in view of Gibbons (US Patent 4,829,011).

Thomas et al., (US Patent 4,749,647) teach methods for a general method for the detection and measurement of analytes in a sample (col. 6 lines 40-43). Interactions or associations between the different analytes are amenable to detection and measurement using different sets of recognition pairs (col. 8 lines 55-59). For example, specific DNA/protein interaction can be assayed under appropriate conditions using a labeled antibody to the protein analyte and a labeled probe for the DNA analyte, one of the two labels being a monomer and the other, a reporter (col. 8 lines 60-65). In general, such determination requires cross-linking of the protein(s) to the nucleic acid and fragmentation of the nucleic acid prior to the assay (col. 8 lines 65-68). Thomas et al., teach immunoassays of the present invention can be performed in any of several configurations (col. 9 lines 3-5). Example V teaches analyte association assays including synthesis and monomerization of analyte detecting sequences. While example V-E teach an assay for p19 protein binding to Rous Sarcoma Virus-RNA (RSV-RNA). This would be a nucleic acid bound to at least one terminus of the polypeptide. The inventors teach using a fluoresceinated anti-p19 antibody to detect the mixture (col. 43 lines 31-32). Thus the antigen is contacted with an antibody. Under this system, fluorescence is incorporated onto the polymer particles (col. 43 lines 40-41). Two controls were run, which showed that there was substantially less incorporation of fluorescence into the polymer particles, indicating that both p19 protein and RSV-RNA

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are required for incorporation of the reporter in to the polymer (col. 43 lines 46-49).

However, Thomas et al., do not recite using an agglutination assay.

Gibbons teaches a method of detecting the presence or amount of agglutination of particles in a reaction medium (col. 2 lines 15-24). The method steps comprise forming a reaction medium containing (1) a sample; (2) a plurality of particles having a binding pair member bound to their surfaces; and (3) a monovalent complementary partner to said binding pair member to which is attached an analyte mimic or analyte binding partner; and detecting the presence of agglutination of said particles in the reaction medium (col. 2 lines 15-24). Examples of such binding pairs include antigens and antibodies and complementary nucleic acid strands (col. 5 lines 38-42).

Agglutination assays do not require expensive detection equipment, can be visually read agglutination, usually qualitative and can be readily adaptable to instrumental quantitation (col.1 lines 28-61).

Therefore, it would have been obvious at the time of applicants invention to modify the method of Thomas et al., who teach methods for binding a nucleic acid to a polypeptide, fixing the nucleic acid bound polypeptide onto the surface of a particle; contacting the antigen with an antibody and detecting the resultant antigen-antibody complex wherein the modification including detection by agglutination immunoassay. No more than routine skill would have been required to perform the agglutination assay since Thomas et al., teach specific binding to polymer particles and measurement of the amount of reporter associated with the particle while Gibbons teaches binding antigens, antibodies and complementary nucleic acid strands to agglutinating agents for use with

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well known agglutination detection techniques. One would have a reasonable expectation of success in modifying the method of Thomas et al., since agglutination assays do not require expensive detection equipment; agglutination assays can be readily adaptable to instrumental quantitation.

Allowable Subject Matter

5. Claims 30 and 32 are allowed.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines *JNH*
October 1, 2004

LFS
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER